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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,765	01/23/2002	Eric Begleiter	70126-47961	8373
21874	7590	08/23/2005	EXAMINER	
EDWARDS & ANGELL, LLP P.O. BOX 55874 BOSTON, MA 02205			TRAN, SUSAN T	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/031,765	Applicant(s) BEGLEITER, ERIC	
	Examiner Susan T. Tran	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-72 is/are pending in the application.
- 4a) Of the above claim(s) 29-72 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____. | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
6) <input type="checkbox"/> Other: _____. |
|---|--|

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-28 rejected under 35 U.S.C. 102(b) as being anticipated by Reif US 4,031,200.

Reif discloses a pharmaceutical dosage forms comprising an edible web or paper and/or polymeric materials having deposited thereon a particulate medicament, the webs being thereafter laminated and finished to pharmaceutically elegant solid dosage forms, such as tablet or capsule (see abstract, column 3, lines 14-36). The web comprises mixture of film-forming compounds, or fibrous ingredients, such as HPMC and HPC (column 7, lines 29-67). Further, the composition comprises plasticizer, and one or more modifying ingredients (column 8, lines 1-52; and column 8, line 55 through column 9, lines 1-17). Reif further discloses the outer most web layer of the dosage form is printed with information (column 32, lines 45 through column 33, lines 1-32).

Response to Arguments

Applicant's arguments filed 03/10/05 have been fully considered but they are not persuasive.

In page 2, second paragraph of applicant's Remarks, applicant indicates that USPN 4,069,086 (Reif '086) was cited by applicant in the initial IDS filed on January 23, 2002, and the Reif '086 patent was considered by Dr. Liliana DiNola-Baron. According to the applicant, Dr. DiNola-Baron found Reif '086 to be in category Y in the international search report, and found claims 1-62 patentable over Reif '086. Applicant further indicates that Dr. DiNola-Baron's first Action on the merits in this case did not cite the Reif '086 patent against any claim. Therefore, applicant argues that the pending claims should be patentable over the Reif '200 as well, because it is a parent application to a divisional Reif '086. In response to applicant's argument, the examiner cannot make any comment over the decision of the predecessor examiner. However, the fact that we may or may not make a mistake in the past does not preclude us from correcting the mistake in the future.

Applicant argues that Reif '200 does not teach holography or putting an image on a standard dosage form. Contrary to the applicant's argument, Reif '200 does teach printing the web by many known method, and the printed web is then laminated into tablet dosage form, or printing can be done on the finished dosage form (column 32, lines 45-62).

Applicant argues that neither Reif '086 or '200 has a teaching or suggestion of a pharmaceutical dosage form that has "a layer of material bearing a microrelief that conveys information, or a core with a solid outer layer and a microrelief in said layer. Nor does either Reif patent have a teaching or suggestion that the material is "thermoformable" to receive this microrelief, or "stable" to maintain the microrelief

Art Unit: 1615

suitable for a pharmaceutical dosage form. In response to applicant's argument, it is noted that Reif '200 teaches Reif '200 discloses pharmaceutical dosage forms made by laminating many layer of edible web containing active ingredients (core), and the outer most layer (microrelief layer) comprises a printing (column 15, lines 35 through column 17, lines 1-63; and column 32, lines 45-62). Regarding the microrelief layer, it is noted that Reif '200 teaches the claimed modified cellulose, e.g., HPMC or HPC (column 7, lines 29-47).

In response to applicant's argument that Reif '200 does not teach the limitations of claims 3 and 19, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963). Regarding the limitation of claim 19, applicant's attention is called to column 8, lines 1 through column 9, lines 1-61, Reif '200 discloses the use of plasticizer, filler, one or more disintegrants, one or more modifying ingredients which effect the electrical, mechanical, optical or permeative properties of the webs produced therefrom. Where the claimed and prior art products are identical or substantially identical in structure or composition, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-R from 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached at (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

Art Unit: 1615

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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SUPERVISORY PATENT EXAMINER
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